USSN 10/512,617, filed 14 January 2005 Attorney Docket No. 1103326-0785 Page 2 of 5

RECEIVED CENTRAL FAX CENTER

FEB 1 1 2009

Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

- 1. (Previously presented) A process for the preparation of a dispersion of nano-crystalline particles in an aqueous medium, the process comprising the steps:
- (a) combining a first solution and an aqueous phase under rapid mixing to form a dispersion of amorphous particles, wherein:
 - (i) the first solution comprises a substantially water-insoluble substance in a watermiscible organic solvent, and
 - (ii) the aqueous phase comprises water and optionally a stabilizer,
- (b) sonicating the dispersion of amorphous particles to form nanocrystalline particles having a mean particle size of from 10 to 280nm of the substantially water-insoluble substance; and (c) optionally removing the water-miscible organic solvent.
- 2. (Previously presented) The process according to claim 1, wherein the nano-crystalline particles have a mean particle size of from 50 to 250nm.
- 3. (Previously presented) The process according to claim 1, wherein the substantially water-insoluble substance is a pharmacologically active compound.
- 4. (Previously presented) The process according to claim 1, wherein the concentration of the substantially water-insoluble substance in the aqueous medium following step (a) is 10 mM or less.
- 5. (Previously presented) The process according to claim 4, wherein the concentration of the substantially water-insoluble substance in the combined solution and aqueous phase following step (a) is from 0.5 to 3 mM.
- 6. (Previously presented) The process according to claim 1, wherein the aqueous phase contains a stabiliser.
- 7. (Previously presented) The process according to claim 6, wherein the stabiliser comprises a polymeric dispersant and an amphiphilic surfactant.

USSN 10/512,617, filed 14 January 2005 Attorney Docket No. 1103326-0785 Page 3 of 5

- 8. (Previously presented) The process according to claim 7, wherein the amphiphilic surfactant is an anionic, cationic, or non-ionic surfactant.
- 9. (Previously presented) The process according to claim 8, wherein the polymeric dispersant is polyvinylpyrrolidone and the anionic surfactant is sodium dodecyl sulfate.
- 10. (Previously presented) The process according to claim 7, wherein the amphiphilic surfactant is at a concentration below the critical association concentration for the amphiphilic surfactant and polymeric dispersant.
- 11. (Canceled)
- 12. (Previously presented) The process according to claim 1, wherein rapid mixing comprises using sonication during the combination.
- 13. (Previously presented) The process according to claim 1, wherein the first solution and the aqueous phase are combined in less than 30 seconds.
- 14. (Previously presented) The process according to claim 1, wherein the first solution is added to the aqueous phase.
- 15. (Previously presented) The process according to claim 1, wherein the dispersion of amorphous particles is sonicated for at least 10 minutes.
- 16. (Previously presented) The process according to claim 1, wherein the dispersion of amorphous particles is sonicated at a temperature below 50°C.
- 17. (Currently amended) The process according to claim 1, further comprising isolating the nano-crystalline particles after formation of the nanocrystalline particles or <u>after</u> removal of the water-miscible organic solvent.
- 18. (Previously presented) The process according to claim 15, wherein the dispersion of amorphous particles is sonicated for 20 to 100 minutes.

USSN 10/512,617, filed 14 January 2005 Attorney Docket No. 1103326-0785 Page 4 of 5

- 19. (Previously presented) The process according to claim 1, wherein: the first solution is added to the aqueous phase, wherein the aqueous phase comprises water, a polymeric dispersant, and an amphiphilic surfactant, and the concentration of the substantially water-insoluble substance in the combined first solution and aqueous phase following step (a) is 10mM or less.
- 20. (Previously presented) The process according to claim 19, wherein the first solution and aqueous phase are combined by rapid mixing using sonication during the combination.